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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/266,154	06/27/94	MORRISON	S BD1CIPFWCIII

18M2/0613

VICKI S VEENKER
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
NEW YORK NY 10020

NISBET, EXAMINER

ART UNIT 41 PAPER NUMBER

1806

DATE MAILED: 06/13/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 3/16/95 This action is made final.

A shortened statutory period for response to this action is set to expire Three month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1. Claims 39-41, 43-48, 54-55, 57-58, 60-69 and 71-95 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims _____ are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other _____

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III. DETAILED ACTION

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. Claims 39-41, 43-48, 54-55, 57-58, 60-69, and 71-95 are rejected under 35 U.S.C. § 103 as being unpatentable over Cabilly (L,R, or 2A) in view of Gillies (Cell 1983).

Rejections are maintained for reasons of record, stated in papers 5, 7, and 10, mailed November 29, 1988, May 24, 1989, and September 25, 1990.

In the response filed 3/16/95, applicants argue that the motivation to combine Gillies and Cabilly does not exist. Cabilly is criticized for failing to actually teach double transfection. Applicants urge that mere recitation of mammalian cells as a host is not sufficient to motivate one of ordinary skill in the art to actually combine Cabilly with Gillies. Gillies is traversed as failing to produce a functional antibody because the transfected heavy chain is of different specificity than the Traversal continues with the argument that the expectation of success is similarly lacking.

These arguments have been considered but are not deemed persuasive. The argument concerning Cabilly is not considered persuasive because of the aforementioned specific teaching of producing antibodies in mammalian cells. See Cabilly (L), pages 18 and 19, for example. While applicants are correct in characterizing Cabilly's disclosure as non-enabling for myeloma cell production, Cabilly is only used to teach double transfection. Gillies shows the production of antibodies in myeloma cells. Moreover, Gillies teaches the production of proteins in yields approaching wild type. Therefore, such yields are considered approximating 100% in comparison to applicant's 32%. Accordingly, applicant's argued unexpected yields are not considered as such. As far as applicant's argument regarding the fact that Gillie's yield is of unassembled protein, such is simply not supported by Gillies. Applicants have not pointed out the statement in Gillies where the routineer would learn that Gillies' protein is not assembled. Absent such a clear disclosure to the contrary, it is more reasonable to assume that Gillies' disclosed yield is functional. Otherwise, Gillies would not be producing the protein. The protein/antibody is of no use when it is not functional.

Applicant's new arguments concerning the alleged failure of Gillies to produce functional antibodies (the exogenous heavy chain is of different specificity than the endogenous light chain, hence the two chains are not complementary) is noted. However, no evidence exists to support applicant's allegation in the 3/16/95 response of nonfunctionality. Moreover, review of the

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Gillies reference does not support applicant's conclusion regarding nonfunctionality. As applicants have stated, Gillies is primarily concerned with the enhancer element, not the actual production of the antibody. Therefore, the reference is basically silent on the issue of heavy chain specificity. Therefore, no evidence exists on the record to support applicant's assertion of nonfunctionality. Further, assuming *arguendo*, that the heavy chain in Gillies is of a separate specificity than the endogenous light chain, one of ordinary skill in the art would merely have to substitute a complementary heavy chain for that set forth in Gillies. The routineer would be motivated to do so because transfection with a complementary would be necessary to yield a binding antibody. Thus Gillies is applied for what it reasonably discloses. That disclosure is the ability of myeloma cells to express, assemble, and secrete exogenous antibody chain. Accordingly, the rejection is maintained for reasons of record.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Nisbet whose telephone number is (703) 308-4204 from 9:00 am to 5:00 pm weekdays with the exception of alternating Mondays. If the examiner cannot be reached, the supervisor, Margaret Moskowitz Parr, may be contacted at phone number (703) 308-2454.

The number for facsimile submission of papers has changed. The new fax number for Art Unit 1806 is (703) 305-7401. Please provide the serial number, application title, examiner's name, and art unit on the fax cover sheet to expedite clerical processing. In addition, all cover sheets should be marked **DRAFT** or **OFFICIAL** as appropriate.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

M. Parr 6/12/95

MARGARET PARR
SUPERVISOR PATENT EXAMINER
GROUP 1800